CASE 4-100-8314C/C1C1

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 336718410US
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April 23, 2004
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE U.S. PATENT NO. 6,306,900 B1

ISSUED: OCTOBER 23, 2001

INVENTORS: BARBARA HAEBERLIN, CHING-PONG MAK, ARMIN MEINZER AND JACKY VONDERSCHER

FOR: ENTERIC-COATED PHARMACEUTICAL COMPOSITIONS

MS Patent Ext.
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR PATENT TERM EXTENSION APPLICATION

Sir:

Enclosed in triplicate is an application for the extension of U.S. Patent No. 4,939,130 under 35 U.S.C. §156.

The Commission is hereby authorized to charge the Application Fee of $1,120.00 prescribed by 37 C.F.R. §1.20(j)(1), as well as any additional fees which may be necessitated in connection with the filing of this Application for Patent Term Extension, to Applicant's Deposit Account No. 19-0134 in the name of Novartis. Two additional copies of this transmittal letter are being submitted for charging purposes.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Thomas R. Savitsky
Attorney for Applicants
Reg. No. 31,661
(862) 778-7909

Date: April 23, 2004

Encl.: Patent Term Extension Application including Appendices A-G in triplicate
Two additional copies of this transmittal letter
Postcard

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PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. §156

Sir:

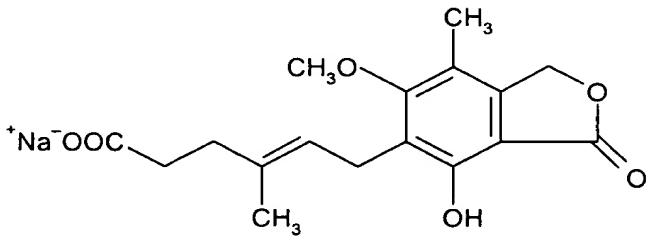
Pursuant to 35 U.S.C. §156 and 37 C.F.R. §1.710 *et seq.*, Novartis AG ("Applicant"), a Corporation organized under the laws of Switzerland, hereby requests an extension of the patent term due to regulatory review of U.S. Patent No. 6,306,900 B1, which was granted on October 23, 2001.

Applicant asserts that it is the owner of the entire right, title and interest in U.S. Patent No. 6,306,900 B1 by virtue of an assignment from the inventors, Barbara Haeberlin, Ching-Pong Mak, Armin Meinzer and Jacky Vonderscher, to Novartis AG. The assignment from the inventors is recorded in the U.S. Patent and Trademark Office at Reel 011257, Frame 0543 on October 30, 2000. Copies of each of these documents evidencing that title to U.S. Patent No. 6,306,900 B1 is vested in Novartis AG are attached hereto as Appendix A.

In accordance with 35 U.S.C. §156 and 37 C.F.R. §1.740, Applicant provides the following information in support of its request for a patent term extension. The following sections are numbered analogously to 37 C.F.R. §1.740.

1. Identification of the Approved Product

The approved product is Myfortic® Delayed-Release Tablets, which contains the active ingredient mycophenolate sodium, having the chemical name (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoic acid sodium salt and having the chemical structure



2. Identification of the Federal Statute Under Which Regulatory Review Occurred

The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, §505(b)(2) [21 U.S.C. §355(b)(2)].

3. The Date of Permission for Commercial Marketing

The approved product received permission for commercial marketing under §505 (c) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. §355(c)] on February 27, 2004. A copy of the United States Food and Drug Administration (FDA) approval letter is attached hereto as Appendix B.

4. Active Ingredient Statement

The sole active ingredient in Myfortic® Delayed-Release Tablets is mycophenolate sodium, which has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act or the Virus-Serum Toxin Act prior to the approval of NDA 50-791 by the FDA on February 27, 2004.

5. Statement of Timely Filing

The last day on which this application could be submitted is April 27, 2004, which is 60 days after the approval of NDA 50-791 on February 27, 2004. This application is timely filed on or prior to April 27, 2004.

6. **Identification of Patent for Which Extension is Sought**

The patent, the term of which the instant application seeks to extend, is a U.S. Patent No. 6,306,900 B1, issued October 23, 2001, having as inventors, Barbara Haeberlin, Ching-Pong Mak, Armin Meinzer and Jacky Vonderscher and entitled ENTERIC-COATED PHARMACEUTICAL COMPOSITIONS, the term of which would otherwise expire on April 10, 2017.

7. **Patent Copy**

A complete copy of U.S. Patent No. 6,306,900 B1, identified in paragraph 6 above, is attached as Appendix C.

8. **Post-Issuance Activity Statement**

No Reexamination Certificate or Reissue has been issued or requested with respect to U.S. Patent No. 6,306,900 B1.

A Certificate of Correction was issued for U.S. Patent No. 6,306,900 B1 on December 24, 2002; a copy of the Certificate of Correction is attached as Appendix D.

A Terminal Disclaimer was filed during the prosecution of the application that matured into U.S. Patent No. 6,306,900 B1; a copy of the Terminal Disclaimer is attached as Appendix E.

9. **Statement Showing How the Claims of the Patent for which Extension is Sought Cover the Approved Product**

Claims 1, 2, 4, 8-12 and 14 cover the approved product. The approved product is mycophenolate sodium in the form of delayed-release tablets that are an enteric-coated formulation of mycophenolate sodium that delivers the active moiety mycophenolic acid. The mycophenolate sodium is in crystalline form. The enteric coating of the tablets contains hypromellose phthalate (hydroxypropyl methylcellulose phthalate). The 180 mg tablet contains 192.4 mg of mycophenolate sodium and the 360 mg tablet contains 384.8 mg of mycophenolate sodium.

Claim 1 covers a pharmaceutical composition comprising a mycophenolate salt, which encompasses mycophenolate sodium, wherein the composition is adapted to prevent release of mycophenolate in the stomach.

Claim 2 claims the composition of Claim 1 having a specific enteric coating which contains hydroxypropyl methylcellulose phthalate.

Claim 4 is directed to the composition of Claim 2 in tablet form.

Claim 8 is directed to the composition of Claim 1 wherein the salt is specifically the mono-sodium salt.

Claim 9 requires the mono-sodium salt to be in crystalline form.

Claim 10 requires the composition to have a specific amount of mycophenolate salt that encompasses the amounts in the approved product.

Claims 11, 12 and 14 contain various combinations of the limitations of the previously-described claims.

10. Statement of the Relevant Dates to Determine the Regulatory Review Period

The relevant dates and information pursuant to 35 U.S.C. §156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

(a) The patent for which extension of the term thereof is sought claims a human drug product. The human drug product is a composition containing mycophenolate sodium.

(b) An Investigational New Drug Application for Myfortic® Delayed-Release Tablets was submitted on September 30, 1998, received by the Department of Health and Human Services on October 1, 1998 and was assigned IND No. 57-005 and became effective on October 31, 1998. The original IND was filed for the prophylaxis of acute transplant rejection in patients receiving allogenic renal transplants. A copy of the IND letter from the FDA is attached as Appendix F.

(c) A New Drug Application for Myfortic® Delayed-Release Tablets was submitted to the Department of Health and Human Services on April 30, 2003 and granted NDA No. 50-791.

(d) NDA No. 50-791 was approved on February 27, 2004.

11. Brief Description of Activities Undertaken During the Regulatory Review Period

As a brief description of the activities undertaken during the applicable regulatory review period, attached hereto as Appendix G is a chronology of the major communications between the FDA and the Applicant in IND No. 57-005 and NDA No. 50-791.

12. Opinion of Eligibility for Extension

Applicant is of the opinion that U.S. Patent No. 6,306,900 B1 is eligible for extension under 35 U.S.C. §156 and 37 C.F.R. §1.720 because it satisfies all of the requirements for such extension as follows:

(a) 35 U.S.C. §156(a) and 37 C.F.R. §1.720(a)

U.S. Patent No. 6,306,900 B1 claims a composition comprising human drug product, mycophenolate sodium. MPEP 2751 states:

> "A patent is considered to claim the product at least in those situations where the patent claims the active ingredient per se, or claims a composition or formulation which contains the active ingredient(s) and reads on the composition or formulation approved for commercial marketing or use."

(b) 35 U.S.C. §156(a)(1) and 37 C.F.R. §1.720(g)

The term of U.S. Patent No. 6,306,900 B1 (expiring April 10, 2017) has not expired before the submission of this application.

(c) 35 U.S.C. §156(a)(2) and 37 C.F.R. §1.720(b)

The term of U.S. Patent No. 6,306,900 B1 has never been extended.

(d) 35 U.S.C. §156(a)(3) and 37 C.F.R. §1.720(c)

The application for extension of the term of U.S. Patent No. 6,306,900 B1 is submitted by the authorized attorney of the owner of record thereof in accordance with the requirements of 35 U.S.C. §156(d) and 37 C.F.R. §1.740.

(e) 35 U.S.C. §156(a)(4) and 37 C.F.R. §1.720(d)

The approved product, Myfortic® Delayed-Release Tablets, has been subjected to a regulatory review period before its commercial marketing or use.

(f) 37 C.F.R. §1.720(h)

No other patent has been extended for the same regulatory review period for the approved product, Myfortic® Delayed-Release Tablets.

(g) 35 U.S.C. §156(a)(5)(A) and 37 C.F.R. §1.720(e)(1)

The permission for the commercial marketing or use of the approved product, Myfortic® Delayed-Release Tablets, is the first received permission for commercial marketing or use of Myfortic® Delayed-Release Tablets under the provision of law under which the applicable regulatory review occurred. A product containing an ester of mycophenolic acid, mycophenolate mofetil, is sold under the trademark CellCept®; however, mycophenolate sodium is not a salt or ester of mycophenolate mofetil [see Glaxo v. Quigg, 13 USPQ2d, 1628 (Fed. Cir. 1990)].

13. **Length of Extension Claimed Under 37 C.F.R. §1.740(a)(12)**

The length of extension of the patent term of U.S. Patent No. 6,306,900 B1 requested by Applicant is 323 days, which length was calculated in accordance with 37 C.F.R.§ 1.775 as follows:

(a) The regulatory review period under 35 U.S.C. §156(g)(1)(B) began on October 31, 1998 (the effective date of the IND) and ended on February 27, 2004, amounting to a total of 1,945 days, which is the sum of (i) and (ii) below:

i. The period of review under 35 U.S.C. §156(g)(1)(B)(i), the "Testing Period", began on October 31, 1998 and ended on April 30, 2003, which is 1,642 days; and

ii. The period for review under 35 U.S.C. §156(g)(1)(B)(ii), the "Application Period", began on April 30, 2003 and ended on February 27, 2004, which is 303 days;

(b) The regulatory review period upon which the period for extension is calculated is the entire regulatory review period as determined in subparagraph (13)(a) above (1,945 days) less:

i. The number of days in the regulatory review period which were on or before the date on which the patent issued (October 23, 2001), i.e., 1,088 days; and

ii. The number of days during which the Applicant did not act with due diligence, i.e., zero days; and

iii. One-half of the number of days remaining in the period in subparagraph (13)(a)(i) after subtracting the number of days in subparagraphs (13)(b)(i) and (13)(b)(ii), which is one-half of (1,642 - [1,088 + 0]) or 277 days,

which results in a period of 1,945 - [1,088 + 0 + 277] = 580 days.

(c) The number of days as determined in subparagraph (13)(b), when added to the original term (April 10, 2017), would result in the date of November 11, 2018.

(d) Fourteen (14) years when added to the date of the NDA Approval Letter (February 27, 2004), would result in the date of February 27, 2018.

(e) The earlier date as determined by subparagraphs (13)(c) and (13)(d) is February 27, 2018.

(f) Since the original patent was issued after September 24, 1984, the extension otherwise obtainable is limited to not more than five (5) years. Five years, when added to the original expiration of U.S. Patent No. 6,306,900 B1 (April 10, 2017), results in the date April 10, 2022.

(g) The earlier date as determined in subparagraphs (13)(e) and (13)(f) is February 27, 2018.

14. Duty of Disclosure Acknowledgement Under 37 C.F.R. §1.740(a)(13)

Applicant acknowledges a duty to disclose to the Commissioner of Patent and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

15. Fee Charge

The prescribed fee for receiving and acting upon this application is to be charged to Applicant's Deposit Account No. 19-0134 as authorized in the attached transmittal letter, submitted in triplicate.

16. Correspondence Address Required by 37 C.F.R. §1.740(a)(15)

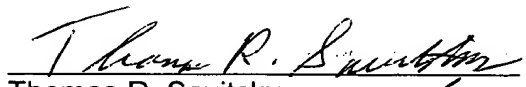
All correspondence relating to this application for patent term extension should be addressed to:

Novartis
Corporate Intellectual Property
One Health Plaza, Bldg. 430
East Hanover, NJ 07936-1080

17. Certification Under 37 C.F.R. §1.740(b)

The undersigned hereby certifies that the instant application, including its attachments and supporting papers, is being submitted as one original and two copies thereof in accordance with 37 C.F.R. §1.740(b).

Respectfully submitted,



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Thomas R. Savitsky
Attorney for Applicants
Reg. No. 31,661
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Date: April 23, 2004